CID 285

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

F B Rice & Co
605 Darling Street
BALMAIN NSW 2041

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PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *day/month/year*	28 OCT 2004
Applicant's or agent's file reference 115091/REH	**IMPORTANT NOTIFICATION**

International Application No.	International Filing Date	Priority Date
PCT/AU2003/000839	30 June 2003	28 June 2002

Applicant
COCHLEAR LIMITED et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	JOSEPH ARROUK Telephone No. (02) 6283 2219

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
115091/REH		
International Application No.	International Filing Date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/AU2003/000839	30 June 2003	28 June 2002
International Patent Classification (IPC) or national classification and IPC		
Int. Cl. [7] A61N 1/05		
Applicant		
COCHLEAR LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☒	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☒	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
14 August 2003	26 October 2004
Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	JOSEPH ARROUK Telephone No. (02) 6283 2219

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU2003/000839

I. Basis of the report

1. With regard to the **elements** of the international application:*

   ☐ the international application as originally filed.

   ☒ the description, pages **1 - 32,** as originally filed,
   pages , filed with the demand,
   pages , received on with the letter of

   ☒ the claims, pages , as originally filed,
   pages **33 - 38,** as amended (together with any statement) under Article 19,
   pages , filed with the demand,
   pages , received on with the letter of

   ☒ the drawings, pages **1/3 – 3/3,** as originally filed,
   pages , filed with the demand,
   pages , received on with the letter of

   ☐ the sequence listing part of the description:
   pages , as originally filed
   pages , filed with the demand
   pages , received on with the letter of

2. With regard to the **language,** all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
   These elements were available or furnished to this Authority in the following language which is:

   ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

   ☐ the description, pages

   ☐ the claims, Nos.

   ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU2003/000839

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☐ claims Nos: **26**

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☒ the claims, or said claims Nos. **26** are so inadequately supported by the description that no meaningful opinion could be formed. **See Box VIII, item 3.**

☐ no international search report has been established for said claim Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1 – 25, 27 – 37	YES
	Claims		NO
Inventive step (IS)	Claims	1 – 25, 27 – 37	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 – 25, 27 – 37	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following document cited in the corresponding ISR:

(a) WO 2003/035168 A1 (COCHLEAR LIMITED), 1 May 2003

NOVELTY (N):

Claims 1 - 25, 27 - 37

The invention defined in claims 1 - 25, 27 - 37 of the present application primarily defines an implantable tissue stimulating device comprising an elongated carrier member having at least a first lumen and further including one or more optic fibres positioned along a length of the first lumen.

Citation (a) discloses an electrode array having a plurality of electrodes mounted thereon in a longitudinal array. The elongated member has a stiffening element extending at least partially therethrough. The stiffening element can extend through a lumen formed in the elongated member and the lead. The lumen preferably extends axially through the elongated member and the lead.

The features defined in claims 1 - 16, 20 - 25, 27 - 37 are not found in citation (a). See however the indication contained in box VI "Certain documents cited" with regard to claims 17 and 18.

INVENTIVE STEP (IS):

As above.

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
P, X WO 2003/035168 A1	1 May 2003	25 October 2002	26 October 2001

The above-listed prior art document discloses all the features defined in claims 17 and 18 of the present application.

See: Abstract; Page 5, line 18 - page 6, line 30; Page 7, line 22 - page 10, line 8.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 12 is not clear because I cannot find an antecedent to the following features: *"The implantable tissue stimulating device"*, page 34, line 17; and *"the one or more optic fibres"*, page 34, line 17.

   Furthermore, the invention defined in claim 12 is not fairly based on what is described in the specification. Claim 12 does not define the invention described because it omits all the essential features. Claim 12 only defines non-essential features which, are described in the preferred embodiments.

   It appears that claim 12 was intended to a dependent on previous claim.

2. The invention defined in claim 17 is not fairly based on what is described in the specification. Claim 17 does not define the invention described because it omits the feature of the elongated carrier including *"one or more optic fibres positioned along a length of said at least a first lumen"*, which from page 5, lines 5 - 6, page 6, line 18, and page 6, line 36, appears to be essential to the invention.

3. The invention defined in claim 26 is not fairly based on what is defined in the specification. Claim 26 does not define the invention described because it omits almost all the essential features of the invention.

   Due to the extreme degree of lack of fair basis I cannot understand the scope of the monopoly being claimed because the definition of the invention is so broad in scope. Therefore, I cannot form an opinion with regard to novelty and inventive step (see Box III).

Art 19

AMENDED CLAIMS

[received by the International Bureau on 19 August 2003 (19.08.03);
claim 19 added ; (6 pages)]

1. An implantable tissue stimulating device comprising an elongate carrier member having a proximal end, a distal end, and a plurality of electrodes mounted thereon between said proximal and distal ends, the elongate carrier member having at least a first lumen extending at least partially therethrough, the elongate carrier member further including one or more optic fibres positioned along a length of said at least a first lumen.

2. The implantable tissue stimulating device of claim 1 comprising a cochlear electrode array.

3. The implantable tissue stimulating device of claim 2 wherein the one or more optic fibres allow a user to illuminate and/or visualise an area of the cochlea during or prior to surgery and wherein further, said one or more optic fibres are removably positioned within said at least a first lumen.

4. The implantable tissue stimulating device of any one of claims 1 to 3 wherein the elongate carrier member includes a plurality of optic fibres.

5. The implantable tissue stimulating device of claim 4 wherein at least one of said plurality of optic fibres allows illumination of a surgical site and at least a further optic fibre allows a user to visualise said surgical site.

6. The implantable tissue stimulating device of any one of claims 2 to 5 wherein the elongate carrier member has a first configuration selected to allow said elongate carrier member to be inserted into the cochlea, and at least a second configuration wherein said elongate carrier member is adapted to apply a preselected tissue stimulation with the electrodes, said elongate carrier member being made of a resiliently flexible first material.

7. The implantable tissue stimulating device of claim 6 wherein the one or more optic fibres act as a stiffening element that biases said elongate carrier member into said first configuration and wherein removal of the stiffening element causes the elongate carrier member to assume its second configuration.

Art 19

8. The implantable tissue stimulating device of claim 6 wherein the elongate carrier member includes a second lumen to receive a stiffening element said stiffening element biasing the elongate carrier member into its first configuration.

9. The implantable tissue stimulating device of claim 3 wherein upon removal of the one or more optic fibres, the at least a first lumen acts as a drug delivery channel.

10. The implantable tissue stimulating device of any one of the preceding claims wherein the elongate carrier member has a resiliently flexible tip member extending forwardly from the distal end of the elongate carrier member, said tip member being light permeable and hemispherical in form.

11. The implantable tissue stimulating device of claim 10 wherein the tip member acts as a lens and allows illumination and/or visualisation of a region at least adjacent the tip member of the elongate carrier member.

12. The implantable tissue stimulating device wherein the one or more optic fibre is connected to an optical fibre termination means said optical fibre termination means including a light source, eyepiece, and/or a camera lens mounted thereto wherein further, said optical fibre termination means receives light output by the light source and directs this light through the one or more optic fibres.

13. An implantable tissue-stimulating device comprising:

an elongate carrier member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said elongate carrier member to be inserted into an implantee's body, and at least a second configuration wherein said elongate carrier member is adapted to apply a preselected tissue stimulation with the electrodes, said elongate carrier member being made of a resiliently flexible first material; and

a stiffening element removably positionable within said elongate carrier member that biases said elongate carrier member into said first configuration;

wherein said stiffening element comprises one or more optic fibres.

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14. The implantable tissue-stimulating device of claim 13 wherein the elongate carrier member extends from a proximal end to a distal end and has a resiliently flexible tip member extending forwardly from the distal end of the elongate carrier member, said tip member being light permeable and hemispherical in form.

15. A cochlear implant electrode assembly device comprising:

an elongate carrier member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said elongate carrier member to be inserted into an implantee's cochlea, and at least a second configuration wherein said elongate carrier member is curved to match a surface of said cochlea, said elongate carrier member being made of a resiliently flexible first material; and

a stiffening element removably positionable within said elongate carrier member that biases said elongate carrier member into said first configuration;

wherein said stiffening element comprises one or more optic fibres.

16. The cochlear implant electrode assembly device of claim 15 wherein the elongate carrier member extends from a proximal end to a distal end and wherein the elongate carrier member has a resiliently flexible tip member extending forwardly from the distal end of the elongate carrier member, said tip member being light permeable and hemispherical in form.

17. A cochlear implant electrode assembly device comprising an elongate carrier member having a proximal end, a distal end, and a plurality of electrodes mounted thereon between said proximal and distal ends, the elongate carrier member having a first configuration selected to allow said member to be inserted into an implantee's cochlea, and at least a second configuration wherein said elongate carrier member is curved to match a surface of said cochlea, said elongate carrier member being made of a resiliently flexible first material and having a lumen formed therein extending from or adjacent the proximal end to or adjacent the distal end and adapted to receive a stiffening element removably positionable within said elongate carrier member that biases said elongate carrier member into said first configuration, wherein said distal end of said elongate carrier member comprises a transparent tip member.

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18. The cochlear implant electrode assembly device of claim 17 wherein said assembly device is pre-packaged with the stiffening element positioned within the lumen of the member.

19. A method of implanting the implantable tissue stimulating device of claim 1, said method including the steps of:

(i) accessing the implantation site; and

(ii) advancing the elongate carrier member into the cochlea whilst using the one or more optic fibres to illuminate and/or visualise a region of the interior cochlea.

20. The method of claim 19 wherein a surgeon manipulates the elongate carrier member to avoid trauma to the tissues of the cochlea.

21. The method of claim 19 or claim 20 wherein once implanted, the electrodes of the elongate carrier member receive stimulation signals from a stimulator means said stimulator means electrically connected to the elongate carrier member by way of an electrical lead.

22. The method of claim 21 wherein the stimulator means is positioned within a housing that is implanted within the implantee and wherein the housing contains in addition to the stimulator means, a receiver means to receive signals from a controller means, said controller means mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

23. The method of claim 22 wherein the signals travel from the controller means to the receiver means and vice versa.

24. A method of implanting the cochlear electrode assembly device of claim 15 or the cochlear electrode assembly device of claim 17 in a body of an implantee, said method including the steps of:

(i) accessing the implantation site; and

(ii) advancing the elongate carrier member into the cochlea.

25. The method of claim 24 wherein as the elongate carrier member is advanced into the cochlea, the surgeon is uses the optic fibre stiffening member to visualise a region of the cochlea.

26. A stiffening element for an implantable tissue-stimulating device characterised in that the stiffening element comprises one or more optic fibres.

27. A probe for use in the internal visual inspection of a cochlea, the probe comprising an elongate carrier member adapted to be at least partially inserted into one of the ducts of the cochlea and having a proximal end, a distal end, and a lumen formed therein, said lumen extending from a location that is at or adjacent the proximal end at least towards the distal end of the elongate carrier member, the probe further including one or more optic fibres removably positioned within at least a portion of the lumen of the elongate carrier member.

28. The probe of claim 27 wherein the lumen extends from a first end to a second end and wherein the first end is at or adjacent the proximal end of the elongate carrier member and the second end is at or adjacent the distal end of the elongate carrier member.

29. The probe of claim 27 wherein the second end of the lumen is open.

30. The probe of claim 27 wherein the second end of the lumen is either partially or wholly closed.

31. The probe of claim 30 wherein the lumen is partially or wholly closed by a light permeable member, said light permeable member comprising one or more lenses that allow visualisation of a region at least adjacent the distal end of the elongate carrier member.

32. The probe of claim 31 wherein the one or more lenses act(s) as a tip member for the elongate carrier member said tip member extending forwardly from the distal end of the elongate carrier member.

33. The probe of any one of claims 27 to 32 wherein the elongate carrier member has a first configuration selected to allow said elongate carrier member to be inserted into an implantee's cochlea and a second configuration wherein the elongate carrier member is curved to at least partially match the curvature of a surface of the cochlea.

34. The probe of claim 33 wherein the first configuration is substantially straight and when in the second position, the elongate carrier member adopts a spiral configuration.

35. A method of inserting the probe of claim 27 in a body of an implantee, comprising the steps of:

(i) accessing the insertion site; and

(ii) introducing the distal end of the elongate carrier member into the cochlea and advancing a substantial length of the elongate carrier member into the cochlea.

36. The method of claim 35 wherein during insertion of the elongate carrier member, a surgeon uses the one or more optic fibres to illuminate and visualise the region of the cochlea adjacent the distal end of the elongate carrier member.

37. The method of claim 35 or claim 36 wherein the probe includes a stiffening member comprising a stylet and wherein during step (ii), the distal end of the elongate carrier member is advanced to a position near the back of the basal turn of the cochlea and subsequently advanced off the stylet such that the distal end of the elongate carrier member is inserted relatively deeper into the scala tympani.